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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/525,808	03/15/2000	Athanasius A Anagnostou	5218-39C	9764
20792	7590	08/10/2004	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

319-
Advisory Action

Application No.

09/525,808

Applicant(s)

ANAGNOSTOU ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 17, 19 and 20.

Claim(s) rejected: 16, 18, 21, 22, 31-33, 35-38 and 40.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


GARY NICKOL
PRIMARY EXAMINER

Christopher Yaen
Art Unit 1642

Response to Amendment After Final

1. The rejection of claims 16, and 31-33 under 35 USC 102 (b) as being anticipated by Silvestris *et al* is maintained for the reasons of record. Applicant argues that the cited reference fails to teach the claimed invention and emphasizes that Silvestris *et al* do not specifically teach a method of treating endothelial injury comprising the addition of endothelial-protecting amounts of erythropoietin (herein epo). Instead, Silvestris *et al* is drawn to a method of "treatment of anemia associated with progressing multiple myeloma." Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. As stated in the prior office action, the specification defines endothelial injury as those injuries caused by the cancer. Because multiple myeloma is a form of cancer and because the specification has included cancer as a cause for endothelial injury, method of treating cancer would also inherently treat endothelial injury. Therefore, because the population of patients administered are the same, and because the method of administering epo would be administered to the same population of patients, the method taught by Silvestris *et al* would inherently treat endothelial injury as claimed.

Applicant also argues that the cited reference is not enabling with regard to treating endothelial injury and that the rejection is based on impermissible hindsight. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to

provide facts rebutting the presumption of operability. In *re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07. In this case, applicant has not provided sufficient evidence to rebut the operability of method anticipated by *Silvestris et al* for treating endothelia injury caused by cancer. Moreover, a reference contains an “enabling disclosure” if the public was in possession of the claimed invention before the date of invention. “Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention.” In *re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985), as is the case with the instantly cited reference of *Silvestris et al*. Furthermore, applicant arguments concerning impermissible hindsight is irrelevant when an 102 rejection is being applied because hindsight arguments only apply in cases of obviousness and not for anticipatory rejections.

2. The rejection of claims 16,18,21,22,31,32,35, and 40 under 35 USC 102(b) as being anticipated by JP 02 096535 to Chugai Pharm Co. Ltd. Is maintained for the reasons of record. Applicant's arguments are substantially similar to those argued above. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. See above (paragraph 1) for response to arguments.

Applicant also argues that the case for inherency has not been established because the reference does not provide inherent characteristics that “necessarily flow from the teachings of the cited art”. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. As

stated above, because the specification has defined endothelial injury as those diseases with are caused by events such as exposure to chemotherapeutics or radiation, the population of patients treated by the method taught in JP 02 096535 and that of the instant claimed method would be the same. Therefore, inherently, treatment of patients with anemia induced by radiation therapy would also inherently treat endothelial damage as instantly, claimed. Therefore, one of skill in the art would necessarily find that the method flowed from the prior art reference. Therefore, the rejection of claim under 35 USC 102 (b) is maintained.

3. The rejection of claims 16,21,31,32,33, and 35-38 under 35 USC 102(b) as being anticipated by Bukowski *et al* is maintained for the reasons of record. Applicant's arguments are substantially similar to those previously argued above (see paragraph 1). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Therefore the rejection of claims under 35 USC 102(b) are maintained.

4. Claims 17 and 19-20 were objected to as being dependent on rejected base claim 16. Applicant argues that claim 16 is patentable and therefore the objection of claims are obviated. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Claim 16 is not patentable and therefore the objection to the claims are maintained.